

Amendments to the Drawings:

The attached replacement drawing sheets makes changes to Figs. 1-3 and replace the original sheets with Figs. 1-3.

Attachment: Replacement Sheets

REMARKS

Claims 1-6 and 8-43 are pending in this application. The Office Action withdraws claims 14 and 22-25 as drawn to non-elected species; withdraws claims 16-18, 27-38 and 42-43 as drawn to non-elected inventions; objects to the Abstract, objects to the Specification; objects to Figures 1-3; rejects claims 1-13, 15, 19-21, 26 and 39-41 under 35 U.S.C. §112, first paragraph; rejects claims 1-13, 15, 19-21, 26 and 39-41 under 35 U.S.C. §112, second paragraph; rejects claims 1 and 39 under 35 U.S.C. §102(b); and rejects claims 1-13, 15, 19-21, 26 and 39-41 under 35 U.S.C. §103(a).

By this Amendment claims 1-6, 8-10 and 39 are amended; claim 7 is cancelled; the Specification is amended; a substitute Abstract is submitted; and Replacement Figures 1-3 are submitted. Support for the amendments to claims 1-6, 8-10 and 39 may be found, for example, in original claim 7. No new matter is added.

I. Informalities regarding the Specification, Abstract and Drawings

A. Priority

The present specification is amended to recite that "This application is a National Stage of PCT/FR03/001919 filed June 23, 2003, and claims priority to French Application Nos. 02/07763, 02/07764 and 02/07765 all filed on June 21, 2002."

Applicants respectfully submit that the requirements of 37 C.F.R. 1.78(a), specifically 37 C.F.R. 1.78(a)(2)(III), were met at the time of filing, because reference to the prior applications was included in the Application Data Sheet. Therefore, the present amendment to the specification is made for clarification only.

B. Abstract

The Office Action objects to the specification for various informalities. A substitute Abstract is submitted herewith. Support for the substitute Abstract may be found, for example, in the Abstract as filed and in the original claims as filed.

Reconsideration and withdrawal of the objection are respectfully requested.

C. Arrangement of the Specification

The Office Action objects to the Specification as lacking the section headers required by 37 C.F.R. 1.77(b). By this Amendment, the specification is amended to include the section headers as provided in 37 C.F.R. 1.77(b).

Reconsideration and withdrawal of the objection are respectfully requested.

D. Drawings

The drawings are objected to because Figures 1, 2 and 3 are allegedly not properly labeled. Replacement Figures 1, 2 and 3 are submitted herewith. Support for these Replacement Figures may be found in the present specification at, for example, paragraphs [0117], [0120] and [0179].

Reconsideration and withdrawal of the objection are respectfully requested.

II. Restriction and Election of Species

Applicants affirm the election of Group I (claims 1-15, 19-26 and 39-41). Applicants further affirm the election of the species involving taurine in combination with polyphenols.

Accordingly, claims 14 and 22-25 are withdrawn in response to the Election of Species Requirement. Claims 16-18, 27-38 and 42-43 are withdrawn in response to the Restriction Requirement.

With respect to the Election of Species Requirement, Applicants understand that upon search, examination and allowance of the elected species, search and examination will continue as to the non-elected species.

III. Information Disclosure Statement

The Office Action alleges that two references listed on the Information Disclosure Statement (IDS) filed May 20, 2005, were not submitted. Specifically, the Office Action alleges that WO 02/24189 and KR 2002 041 348 were not provided.

Applicants respectfully submit that both WO 02/24189 and KR 2002 041 348 were provided, and are of record as shown in the Image File Wrapper in the USPTO's Patent Application Information Retrieval (PAIR) system. Specifically, document WO 02/24189 is the "Foreign Reference" submitted 5-20-2005 that is 32 pages long, and is the second "Foreign Reference" from the top after the IDS filed 5-20-2005 as shown in the Image File Wrapper. Document KR 2002 041 348 is the "Foreign Reference" submitted 5-20-2005 that is 1 page long, and is the eleventh reference from the top after the IDS filed 5-20-2005 as shown in the Image File Wrapper. Applicants note that each of these documents contains an English language abstract therein.

The Office Action also alleges that several documents cited in the IDS filed May 20, 2005 fail to comply with the relevant rules because they are in a foreign language and no English language translation was provided. First, Applicants note that the Office Action identified the filing date of the IDS as February 10, 2005 (see Office Action page 6, item 7), however Applicants assume that the Office Action is referring to the May 20, 2005 IDS because no IDS was filed on February 10, 2005. Specifically, the Office Action states that documents FR 2 734 477, FR 2 581 542, EP 0 064 012, EP 0 353 123, EP 0 356 271, EP 0 408 442, EP 0 522 964, EP 0 420 707, EP 0 489 890, EP 0 519 819 and DE 202 04 844 were not considered as to the merits because they are in a foreign language.

Applicants respectfully submit that the IDS filed May 20, 2005 and the foreign language references cited therein are in full compliance with 37 C.F.R. 1.98. First, Applicants note that no rule under 37 C.F.R. nor any practice under the MPEP requires an English *translation* of a foreign language reference cited in an IDS. Instead, 37 C.F.R. 1.98(a)(3)(i) states that an IDS need only include a "concise explanation of the relevance" of each reference not in the English language. Furthermore, "[t]he concise explanation may be either separate from applicant's specification or incorporated therein." Applicants respectfully

submit that all of the above listed documents, except for FR 2 734 477 and DE 202 04 844, are discussed in the present specification at least at pages 18-20. The IDS filed May 20, 2005 stated in paragraph 2 that the relevance of the references is discussed in the present specification. Therefore, the discussion of these documents in the specification constitutes "a concise explanation of the relevance" such that they *must* be considered by the Examiner.

Additionally, with respect to FR 2 734 477 and DE 202 04 844, Applicants note that these two documents were cited in the International Search Report of the related PCT application. An English language version of the International Search Report was submitted with the IDS filed May 20, 2005, and correlated to these references in paragraph 3 of the IDS. Under MPEP §609A(3), where the references are cited in a search report in a counterpart foreign application, "the requirement for a concise explanation can be satisfied by submitting an English-language version of the search report or action which indicates the degree of relevance found by the foreign office."

Therefore, the IDS filed May 20, 2005, fully complied with the applicable rules such that all of the references cited therein must be considered by the Examiner. The Examiner is requested to initial and return to the undersigned a copy of the subject Form PTO-1449, confirming that the cited references have been considered of record. For the convenience of the Examiner, a copy of that form is attached.

IV. Rejections under 35 U.S.C. §112

A. Written Description

Claims 1-13, 15, 19-21, 26 and 39-41 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office Action alleges that "Applicant has failed to provide any disclosure as to what Applicants contemplate 'aging' is."

In the interest of advancing prosecution, and without admitting the priority of the rejection, claims 1-6, 8-10 and 39 are amended so as to no longer recite "aging of the philosebaceous unit."

Reconsideration and withdrawal of the rejection are respectfully requested.

B. Enablement

Claims 1-13, 15, 19-21, 26 and 39-41 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicants respectfully traverse the rejection.

Applicants respectfully submit that the full scope of the amended claims is enabled such that a person having ordinary skill in the art can make and use the presently claimed invention without undue experimentation. Specifically, Applicants submit that the scope of the enablement provided to one skilled in the art is entirely commensurate with the scope of protection sought by the presently amended claims. See MPEP 2164.04.

To begin with, Applicants note that amended independent claims 1, 4, 5, 6 and 39 recite a narrower breadth of scope than the rejected claims. These claims now recite "miniaturization of the hair follicle" or disorders of the hair relating directly to collagens (see claims 4-6). Applicants respectfully submit that this scope is enabled by the present specification in view of the knowledge of a person having ordinary skill in the art.

Specifically, Applicants first note that the state of the prior art showed that disorders of the hair can be related to collagen formation. For example, Mahe et al., Androgenetic Alopecis and Microinflammation, International Journal of Dermatology, Vol. 39, Issue 8, pages 576-580 (2000) states that "the miniaturization of the hair follicles was found to be associated with a deposit of so called 'collagen or connective tissue streamers' beneath the follicle." A copy of this article is attached. See also T. Shigematsu et al., Biochimica et Biophysica Acta 1200 (1994) 79-83) cited in the present specification at page 25, line 25, for

discussion of how rigidification, i.e. fibrosis, is linked to collagen metabolism and in particular to collagen secretion.

Accordingly, the presently claimed invention achieves treatment or prevention of the recited collagen associated disorders of the hair because, as is shown in the specification, "taurine reduces the incorporation of proline without impairing that of leucine; this shows the advantage of taurine for specifically reducing the accumulation of collagen, without impairing the overall synthesis of proteins." Specification page 4, lines 9-13.

This result is shown in the Example on pages 25-26 of the present specification. Table 1 on page 26 shows that taurine significantly inhibits the incorporation of proline by the fibroblasts, wherein proline incorporation is representative of collagen synthesis. Page 26, lines 19-26. These results therefore show that administration of taurine can be correlated to miniaturization of the hair follicle, impairment of the hair follicle induced by excessive crosslinking and/or synthesis of natural collagens, regulation of the metabolism and structure of collagens in perifollicular skin and regulation of the metabolism and structure of collagens in the connective sheath of the hair follicle, because all of these disorders are related to collagen formation, and taurine inhibits collagen formation.

Applicants acknowledge that this Example was conducted *in vitro* using cultured fibroblasts (specification page 25, lines 28-32). However, Applicants strongly traverse the Office Action's assumption that "the taurine and/or hypotaurine or their salts is required to be assessed for physiological activity by *in vivo* screening" (emphasis added). Applicants assert that *no such requirement exists* under 35 U.S.C. §112, first paragraph. On the contrary, under MPEP 2164.02, when "the art is such that a particular model is recognized as correlating to a specific condition, then it should be accepted as correlating unless the examiner has evidence that the model does not correlate." In this case, *in vitro* models are known in the art to correlate to *in vivo* conditions. For example, an article by the present inventors and others,

Collin et al, "Protective Effects of Taurine on Human Hair Follicle Grown in Vitro," International Journal of Cometic Science, 28(4), pages 289-98 (2006) states that human hair follicles grown *in vitro* recapitulate most of the characteristic features of normal hair follicles in vivo. A copy of the abstract of this article is attached. Applicants acknowledge that the date of this article is after the filing date of the present application; however, this article is cited merely to show that the *in vitro* model was widely known to accurately correlate to *in vivo* conditions.

Accordingly, in view of these disclosures and the known art regarding hair disorders, a person of ordinary skill in the art can make and use the presently claimed invention without undue experimentation. Applicants note that a patent may be enabling even though some experimentation is necessary, as long as the amount of the experimentation is not unduly extensive. Utter v. Hiraga, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988). Furthermore, "a specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support," MPEP 2164.04, emphasis added. The Office Action has shown no reason to doubt the objective truth of the statements made in the specification regarding the results of the experiments therein, and so the full scope of the amended claims is enabled.

Reconsideration and withdrawal of the rejection are respectfully requested.

C. Indefiniteness

Claims 1-13, 15, 19-21, 26 and 39-41 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Specifically, the Office Action alleges that the term "aging" is indefinite.

Without admitting the propriety of the rejection, and in the interest of advancing prosecution, claims 1-6, 8-10 and 39 are amended to remove the term "aging."

Reconsideration and withdrawal of the rejection are respectfully requested.

V. Rejection under 35 U.S.C. §102(b)

Claims 1 and 39 are rejected under 35 U.S.C. §102(b) as anticipated by Kisters (U.S. Patent No. 6,331,569). Applicants respectfully traverse the rejection.

Applicants respectfully submit that Kisters does not disclose all the features of amended independent claims 1 and 39. Specifically, Kisters at least fails to disclose that the taurine, hypotaurine, and salts thereof are the *sole* active amino acid. See the present specification at, for example, page 17, lines 23-28, and page 26, Table 1, and page 27, Example 1. Instead, Kisters requires the presence of valine, leucine, isoleucine and proline. Kisters at column 4, lines 17-18, also see Kisters claim 1.

Furthermore, Kisters also does not disclose that the oral composition comprises at least 21.7 wt % of the taurine, hypotaurine, and/or salts thereof. See the present specification at, for example, page 41, Example 26 and page 6, lines 25-26. Specifically, see 150 mg of taurine, where $150/(150+375+150+15) = 0.217 = 21.7 \text{ wt } \%$. Instead, Kisters merely discloses that taurine can comprise up to 10 wt % of the oral composition therein. See Kisters at column 6, line 14 and claim 9.

Accordingly, independent claims 1 and 39 are not anticipated by Kisters, for at least the reasons discussed above.

Reconsideration and withdrawal of the rejection are respectfully requested.

VI. Rejection under 35 U.S.C. §103(a)

Claims 1-13, 15, 19-21, 26 and 39-41 are rejected under 35 U.S.C. §103(a) as having been obvious over Kisters in view of Duranton (WO 2004/034820). Applicants respectfully traverse the rejection.

Applicants respectfully submit that Duranton is not prior art to the present application. Specifically, Duranton has a prior art date as of its publication on April 29, 2004. However, the present application is a National Stage application from PCT/FR03/001919 filed on June 23, 2003. This priority was indicated on the Application Data Sheet at the time the present application was filed, in accordance with 37 C.F.R. 1.98(a)(2)(III). Therefore, in accordance with 35 U.S.C. §363, the present application has an effective U.S. filing date of June 23, 2003. Therefore, Duranton is not prior art.

Furthermore, Applicants note that U.S. Patent Application Publication No. 2006/0035846, a continuation of the Duranton PCT application, (hereinafter "Duranton '846"), is also not prior art for purposes of 35 U.S.C. §103 in accordance with 35 U.S.C. §103(c). Specifically, Duranton '846 is a continuation of the above discussed PCT application and claims priority to a provisional application, application serial no. 60/441,762, filed on January 23, 2003. Therefore, even if this provisional application supports the disclosures that might be relied upon, Duranton '846 would at most qualify as prior art under 35 U.S.C. §102(e). However, under the provisions of 35 U.S.C. §103(c), Duranton '846 is disqualified as prior art under 35 U.S.C. §103 because both Duranton '846 and the present application "were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person."

Duranton '846 is assigned to L'Oreal and Nestec S.A., this assignment is recorded at reel 016956, frame 0361. The present application is also assigned to L'Oreal and Nestec S.A., this assignment is recorded at reel 015876, frame 0272. Furthermore, the present application and Duranton '846 were, at the time the invention was made, owned by, or subject to an obligation of assignment to, L'Oreal and Nestec S.A.. Therefore, Duranton '846 is disqualified from being used as a reference under 35 U.S.C. 103(a).

Accordingly, because Duranton WO 2004/034820 is not prior art, and no reference based thereon qualifies as prior art for a rejection under 35 U.S.C. §103, the rejection is overcome and must be withdrawn. Specifically, the presently claimed invention would not have been obvious over Kisters alone as discussed above.

Reconsideration and withdrawal of the rejection are respectfully requested.

VII. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the application are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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WPB:STD/std

Enclosures:

Abstract
Replacement Sheets 1-3
PTO Form 1449 filed May 20, 2005
Mahe et al., "Androgenetic Alopecia and Microinflammation," International Journal of Dermatology, Vol. 39, Issue 8, pages 576-580 (2000)
Collin et al, "Protective Effects of Taurine on Human Hair Follicle Grown in Vitro," International Journal of Cosmetic Science, 28(4), pages 289-98 (2006), abstract only

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